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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,272	07/17/2003	Shanta M. Modak	070050.2429	4202

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/622,272	MODAK ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13,15,17,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-13, 15, 17, and 31-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 4/28/2008, are acknowledged and entered. Claims 31 and 32 are newly presented. Claims 1-9, 11-13, 15, 17, and 31-32 are pending and under examination.

Claim Objections

The objection to claim 1 because the word "farsenol" was misspelled in line 4 is withdrawn in view of Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-8, 11-13, 15, 17, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Modak *et al.*** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) and **Dodd *et al.*** (U.S. Patent No. 6,344,218; Issued Feb. 5, 2002; Filed May 27, 1999) in view of **Luebbe *et al.*** (U.S. Patent No. 5,902,572; Issued May 11, 1999).

The instant claims recite compositions comprising two or more water-soluble organic salts of zinc, an antimicrobial agent, farnesnol, and further comprising water, ethanol, and one or

more agents selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient.

Modak *et al*. teach of the use of organic salts of zinc in topical formulations (Abstract). Organic salts of zinc include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laurate, zinc stearate, zinc lactate and zinc propionate (col. 1, lines 56-60). These are the same organic zinc salts recited in instant claim 2. The organic salts of zinc may be comprised in a cream base, which may be hydrophilic or hydrophobic (col. 2, lines 8-9). Said cream bases are known to include water, dimethicone, glycerin and other excipients (*id*. at lines 10-26). The concentration of organic salts of zinc may vary from between 1 to 15% and in a particular embodiment, may comprise 0.1 to 1% zinc salicylate (*id*. at lines 27-30 and lines 36-45)). This teaches the limitation recited in claim 1. Further, in addition to zinc salicylate, the compositions may comprise "one or more other organic salts of zinc, thus teaching the limitation "two or more" as recited in instant claim 1 (*id*. at lines 30-31). With respect to the amounts of water and emollients recited in the instant claims, if the compositions taught in Modak *et al*. comprise about 1 to 15% organic zinc salt in a cream base, the remaining percentage must be comprised of water and emollients. Modak *et al*. do not teach compositions further comprising an antimicrobial compound and farnesnol.

However, Dodd *et al*. teach of aqueous compositions comprising an odor controlling agent and select sanitizing agents (Abstract). A preferred composition comprises an effective amount of an odor controlling agent, from 40% to 99% of an alcohol antiseptic, from 0 to 10% of a water-soluble metallic salt, from 0 to 10% of a thickener, from 0 to 10% of an emollient, from 0 to 1% of perfume and water (col. 2, lines 24-33). Water-soluble metallic salts are taught to be useful as odor controlling agents (col. 3, lines 45-46). Specifically, preferred metallic salts include zinc gluconate, zinc lactate and zinc salicylate as recited in instant claim 2 (col. 6, lines 10-12). The metallic salts are present in the compositions in amounts ranging from 0.01% to 10%, preferably 0.3% to 5% (*id*. at lines 17-25). The compositions taught in Dodd *et al*. comprise between 5% and 70% water, thus teaching the limitations of instant claim 3 (col. 10, lines 32-35). Optionally, but preferably, emollients can be added to the compositions, including silicone oils, branched hydrocarbons, petrolatum, dimethicones and dimethiconols (elected specie) and polyethylene glycol (*id*. at lines 48-49 and 51). The emollients comprise from 0.5%

to 50%, more preferably 0.5% to 10% by weight of the compositions, thus teaching the limitations of claims 4 and 5 (*id.* at lines 63-66). Optionally, but preferably, thickeners can be added to the compositions of the invention (col. 11, lines 1-2). Said thickeners include polymeric materials (*e.g.* starch) and hydroxyethyl cellulose as recited in instant claim 7 (*id.* at lines 33 and 35). The thickeners comprise from 0.01% to 10%, preferably 0.1% to 5% by weight of the compositions, thus teaching the limitations of claims 6 and 7 (col. 12, lines 8-14). Surfactants, including silicone surfactants (*e.g.* dimethyl polysiloxane hydrophobic polymers) are taught at column 16, line 65 to column 19, line 45. The amounts of surfactants range from 0% to 20%, most preferably 0.25% to 2.5% (col. 19, lines 46-49). The reference thus teaches the limitations of claims 8, 12-13 and 15. Antimicrobial agents, including benzalkonium chloride (elected specie), chlorhexidine salts, and mixtures thereof are taught at column 8, lines 8-25 and 33-35. When chlorhexidine and its salts are used, they are present in amounts ranging from 0.001% to 0.4% (col. 8, lines 38-42). This teaches the limitations of instant claim 11. Antioxidants are taught at column 24, line 45, thus teaching the limitations of claims 12-13. The examples shown at column 26 to column 30 include ethanol, thus teaching a further limitation of instant claim 1. Dodd *et al.* do not teach compositions further comprising farnesol.

However, Luebbe *et al.* teach gel deodorant compositions comprising deodorant actives that also act as antimicrobial agents, such as zinc salts and farnesol (elected specie) (Abstract; col. 3, lines 6-21).

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed compositions would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. In the instant case, the combined references teach all of the limitations of the claimed compositions and provide one skilled in the art with the motivation to combine the teachings of the individual references to arrive at the claimed subject matter. The prior art teaches that organic salts of zinc can be used in topical formulations so as to decrease skin irritation (Modak *et al.*). Dodd *et al.* teach odor-controlling compositions comprising zinc salts and antimicrobial agents. With respect to farnesol, farnesol and zinc salts are art-recognized deodorant and antimicrobial agents as evidenced by Luebbe *et al.* Accordingly, it would have been obvious to use farnesol in the odor-controlling/anti-microbial compositions taught in Dodd *et al.* The motivation to combine the teachings of

Modak *et al.*, Dodd *et al.*, and Luebbe *et al.* would be to formulate a composition having odor-controlling/anti-microbial properties while at the same time minimizing irritation often caused by traditional topical compositions. The skilled artisan would appreciate that the addition of water-soluble zinc salts as taught in Modak *et al.* to the odor-controlling/anti-microbial compositions taught by Dodd *et al.* and Luebbe *et al.* would predictably achieve this result.

Applicant's arguments have been considered but they are not persuasive. Applicant argues that he has discovered that unlike compositions comprising high zinc salt concentrations, the low zinc salt concentrations of the invention do not interfere with the antimicrobial activity of antimicrobial agents present in the same composition. Referring to Example 5 of the instant application, Applicant argues that a high concentration of zinc salts exhibits a reduction in the effectiveness of an antimicrobial agent present in the composition. However, contrary to Applciant's characterization of Example 5, nowhere is a comparison between a "high" concentration of zinc salts and "low" concentration of zinc salts made. Example 5 only relates to a specific formulation comprising 1% CHG, 50% ethanol, 50% propylene glycol and 2% zinc gluconate. Nowhere in Applicant's specification is a comparison made between the compositions suggested and motivated by the prior art as discussed supra and the claimed compositions. Further, it is noted that Modak et al. suggest that the amount of zinc salts in topical formulations can be in the range of 1 to 15% with a particular embodiment containing 0.1 to 1% zinc salicylate. Accordingly, the Examiner is not persuaded that Applicant has demonstrated an unexpected property of the claimed compositions in comparison to the compositions suggested and motivated by the prior art.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Modak *et al.*** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999), **Dodd *et al.*** (U.S. Patent No. 6,344,218; Issued Feb. 5, 2002; Filed May 27, 1999), and **Luebbe *et al.*** (U.S. Patent No. 5,902,572; Issued May 11, 1999) as applied to claims 1-4, 6-9, 11-13, 15, 17, and 31-32 above, and further in view of **O'Laughlin *et al.*** (U.S. Patent No. 4,868,169; Issued Sep. 19, 1989).

Claim 5 differs from Modak *et al.*, Dodd *et al.*, and Luebbe *et al.* in that the cited references do not explicitly teach the instantly claimed Glucam P-20.

However, O'Laughlin *et al.* teach cream formulations optionally comprising skin conditioners or humectants, including the instantly claimed Glucam P-20 (col. 3, lines 59-66).

Accordingly, it is apparent that Glucam P-20 was known in the art as a skin conditioning agent or humectant suitable for incorporation into topical creams. As such, it would have been obvious to substitute Glucam P-20 for any of the emollients as recited in Modak *et al.* and Dodd *et al.* The motivation to do so is found in O'Laughlin *et al.* who teach that Glucam P-20 is useful as a skin conditioning agent in topical cream formulations.

Applicant's arguments have been considered but they are not persuasive. Applicant argues that O'Laughlin provides no disclosure regarding zinc salts nor concentrations at which zinc salts are effective anti-irritants. This argument is not persuasive because it is the *combined* references that teach and suggest the claimed compositions, not O'Laughlin by itself.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Modak *et al.*** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999), **Dodd *et al.*** (U.S. Patent No. 6,344,218; Issued Feb. 5, 2002; Filed May 27, 1999), and **Luebbe *et al.*** (U.S. Patent No. 5,902,572; Issued May 11, 1999) as applied to claims 1-4, 6-9, 11-13, 15, 17, and 31-32 above, and further in view of **Turner *et al.*** (U.S. Patent No. 5,073,372; Issued Dec. 17, 1991).

Claim 9 differs from Modak *et al.*, Dodd *et al.*, and Luebbe *et al.* in that the cited references do not explicitly teach the instantly claimed dimethiconol fluid in dimethicone silicone polymer.

However, Turner *et al.* teach facial emulsion formulations comprising non-volatile organopolysiloxanes, including the instantly claimed dimethiconol fluid in dimethicone (col. 6, lines 33-56, especially line 55).

Accordingly, it is apparent that dimethiconol fluid in dimethicone was known in the art as a non-volatile organopolysiloxanes suitable for incorporation into topical creams. As such, it would have been obvious to substitute dimethiconol fluid in dimethicone for any of the silicone oils as recited in Dodd *et al.* The motivation to do so is found in Turner *et al.* who teach that dimethiconol fluid in dimethicone is a useful excipient in topical skin care compositions.

Applicant's arguments have been considered but they are not persuasive. Applicant argues that Turner is silent with regard to the effect of zinc salt concentration on preventing

irritation or on the efficacy of antimicrobial agents. This argument is not persuasive because it is the *combined* references that teach and suggest the claimed compositions, not Turner by itself. Further, Applicant's characterization of the properties of the claimed compositions do not result in a patentable distinction between the compositions suggested and motivated by the prior art and the claimed compositions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 5,965,610

Claims 1-9, 11-13, 15, 17, and 31-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-8 and 11-15 of U.S. Patent No. 5,965,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of the '610 patent claims allows for the presence of other agents, including the antimicrobials and silicone polymers recited in the instant claims. Further, the instantly claimed concentrations are encompassed by the '610 patent claims.

Applicant submits that "appropriate action" will be taken as the Examiner indicates allowable subject matter in the instant application. The Examiner reminds Applicant, however, that no allowable subject matter can be indicated in the instant application while the claims remain rejected on the ground of nonstatutory obviousness-type double patenting.

U.S. Patent No. 5,985,918

Claims 1, 3-9, 11-13, 15, 17, and 31-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,985,918. The '918 patent claims a topical composition comprising zinc stearate and zinc salicylate in a "topical cream base". Although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of the '918 patent claims allows for the presence of other agents, including the thickeners, emollients, antimicrobials and silicone polymers recited in the instant claims.

Applicant submits that "appropriate action" will be taken as the Examiner indicates allowable subject matter in the instant application. The Examiner reminds Applicant, however, that no allowable subject matter can be indicated in the instant application while the claims remain rejected on the ground of nonstatutory obviousness-type double patenting.

Application No. 10/892,034

Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-19 and 39-42 of copending Application No. 10/892,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass compositions comprising two or more organic zinc salts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant submits that "appropriate action" will be taken as the Examiner indicates allowable subject matter in the instant application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614